510(k) Summary: Oral Fluid Amphetamine Assay

K110446

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

MAY - 3 2011

Submitter Name, Address, Contact

Roche Diagnostics
9115 Hague Rd.
Indianapolis, IN 46250
317-521-3742

Contact Person: Michelle Neff
Date Prepared: April 11, 2011

Device Name

Proprietary name: Oral Fluid Amphetamine Assay

Common name: Amphetamine test system

Classification name: Enzyme Immunoassay, Amphetamine

Product Code: DKZ

Device Description

The DAT oral fluids assays are based on the kinetic interaction of microparticles in a solution (KIMS) technology. The DAT oral fluids assays are qualitative and semi-quantitative. In the absence of sample drug, soluble drug conjugates bind to antibody-bound microparticles, causing formation of particle aggregates. As the aggregation reaction proceeds in the absence of sample drug, the absorbance increases. When an oral fluid sample contains the drug in question, this drug competes with the drug derivative conjugate for microparticle-bound antibody. Antibody bound to sample drug is no longer available to promote particle aggregation, and subsequent particle lattice formation is inhibited. The presence of sample drug diminishes the increasing absorbance in proportion to the concentration of drug in the sample. Sample drug content is determined relative to the value obtained for a known cutoff concentration of drug.

Multi-analyte calibrator and control solutions are prepared from NIST traceable, commercially available solutions. A stock solution is prepared gravimetrically and verified by LC/MS/MS. The product calibrators are prepared gravimetrically in a synthetic oral fluid matrix at the following concentrations: 0, 20, 40, 80, 160, and 320 ng/mL. Controls are prepared gravimetrically in a synthetic oral fluid matrix at concentrations ±50% of the cutoff. All calibrator and controls concentrations are verified by LC/MS/MS.

Intended Use

DAT Oral Fluid Amphetamine (OFAMP) is an in vitro diagnostic test for the qualitative and semiquantitative detection of amphetamine in human oral fluid at a cutoff concentration of 120 ng/mL in neat oral fluid. The specimen must be collected exclusively with the Intercept® Oral Specimen Collection Device. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program and to estimate a dilution of the specimen for confirmation by a confirmatory method such as LC/MS/MS.

DAT Oral Fluid Amphetamine provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Chromatography/mass spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The Oral Fluid DAT Control Set B is for use as assayed controls with the DAT Oral Fluid assays on automated clinical chemistry analyzers for human oral fluid samples collected with the Intercept® Oral Specimen Collection Device.

The Oral Fluid DAT Qual Cal B calibrators are designed for the calibration of oral fluid assays for drugs of abuse on automated clinical chemistry analyzers for human oral fluid samples collected with the Intercept® Oral Specimen Collection Device.

The Oral Fluid DAT SQ Cal B calibrators are designed for the calibration of oral fluid assays for drugs of abuse on automated clinical chemistry analyzers for human oral fluid samples collected with the Intercept® Oral Specimen Collection Device.

Comparison to Predicate Device

The Oral Fluid Amphetamine assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, we claim substantial equivalence to the currently marketed Amphetamine-Specific Intercept® Micro-Plate EIA assay (K992918).

Comparison Table

Feature	Roche Oral Fluid Amphetamine Assay	Predicate Device: Amphetamine-Specific Intercept® MICRO-PLATE EIA (K992918)
Methodology	KIMS, Kinetic interaction of microparticles in solution	Competitive micro-plate immunoassay
Sample Type	Oral Fluid	Oral Fluid
Intended Use	Qualitative and semi-quantitative detection of Amphetamine	Qualitative detection of Amphetamines
Neat Cutoff	120 ng/mL in Neat Oral Fluid	100 ng/mL when oral fluid collected with the Oral Specimen Collection Device
Controls	Synthetic oral fluid matrix: Zero, Negative (.5X), and Positive (1.5X)	Synthetic oral fluid matrix: Negative (.5X) and Positive (2X)
Calibrator	Synthetic oral fluid matrix: Zero, .5X, Cutoff, 2X, 4X, and 8X	Synthetic oral fluid matrix: Zero, Cutoff

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAY 3 2011

Roche Diagnostics
c/o Ms. Michelle Lee Neff
Regulatory Affairs Principal
9115 Hague Road, PO Box 50416
Indianapolis, IN, 46250-0416

Re: k110446
Trade Name: DAT Oral Fluid Amphetamine Assay, Oral Fluid DAT Qual Cal B, Oral Fluid DAT SQ Cal B and Oral Fluid DAT Control Set B
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: DKZ, DKB, DIF
Dated: February 15, 2011
Received: February 16, 2011

Dear Ms. Neff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K110446

Device Name: **Oral Fluid Amphetamine**
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Prescription Use ___XXX___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110446